REMARKS

Claims 1, 3-16, 18, 20-31 are pending. Claims 32-34 have been canceled without prejudice and without acquiescence as they are drawn to non-elected subject matter. Claims 2, 17 and 19 have been canceled without prejudice and without acquiescence. Claims 1, 18, 20 and 21 have been amended without prejudice and without acquiescence to clarify the claim scope. Applicants retain the right to file any divisional and/or continuation applications from any canceled subject matter. No new matter has been added.

The issues outstanding in this application are as follows:

- The specification is objected to as containing informalities.

- Claims 1-2 and 11-31 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

- Claims 1-3 and 10-12 have been rejected under 35 U.S.C. §102(b), as being anticipated by Cianflone et al. (Atherosclerosis, vol. 120, 1996, pages 101-114).

- Claims 1-12, 14, 17-19 and 26 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Nuijens et al. (U.S. Patent No. 6,333,311).

Applicants respectfully traverse the outstanding rejections and objections, and applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Objections to Specification

The Examiner has requested that the specification be corrected as it contains trademarks. Applicants note that in section 608.01(v) of the it indicates that trademarks can be identified by either capitalizing each letter of the word in the bracket OR include a proper trademark symbol, such as [trade] or ® following the word. Applicants have included the ® after each trademark, thus it is not necessary to capitalize each letter.

In some instances, the trademarks were not accompanied by the generic terminology, thus, as requested by the Examiner, Applicants have amended the specification. No new matter has been added.

II. U.S.C. §112, second paragraph

Claims 1-2 and 11-31 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended without acquiescence and without prejudice claim 1. In view of these amendments, Applicants request withdrawal of the rejection.

III. 35 U.S.C. §102(b)

Claims 1-3 and 10-12 have been rejected under 35 U.S.C. §102(b), as being anticipated by Cianflone et al. (Atherosclerosis, vol. 120, 1996, pages 101-114). Applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended without acquiescence and without prejudice claim 1 to indicate that the lactoferrin composition is administered orally or parenterally. Applicants assert that Cianflone et al. does not identify, mention or suggest oral or parenteral administration of lactoferrin, at best Cianflone et al. teaches in vitro administration of lactoferrin to a cell line, which does not relate to in vivo administration of lactoferrin. If the Examiner continues to maintain this rejection, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in the Cianflone et al.. *See, In re Gartside,* 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Thus, in view of the amendments contained herein, Applicants assert that Cianflone et al. do not anticipate independents claim 1, 3 and 10-12, and thus, Applicants respectfully request that the rejection be withdrawn.

IV. 35 U.S.C. §103(a)

Claims 1-12, 14, 17-19 and 26 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Nuijens et al. (U.S. Patent No. 6,333,311). The Examiner indicates that Nuijens et al. disclose treating cardiovascular diseases. Applicants traverse.

Applicants remind the Examiner that a *prima facia* case necessitates disclosure of the source for either a suggestion or motivation to modify a reference to produce the present invention, and a reasonable expectation of success of producing the present invention. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

In order to advance the prosecution of the present application, Applicants have amended without acquiescence and without prejudice claim 1 to indicate that the cardiovascular disease is atherosclerosis or vascular inflammation.

In view of this amendment, Applicants assert that the pending claims are non-obvious. Applicants contend that the Examiner has mischaracterized the teachings of Nuijens et al. Nuijens et al. may mention "reducing reperfusion injury in a patient after myocardial infarction," however, this does not suggest treating atherosclerosis or vascular inflammation (See Nuijens column 2, lines 23-25). Reperfusion injury is defined as the damage that occurs upon reperfusion after ischemia. During ischemia, there is an absence of oxygen and nutrient in tissue which creates a condition in which the restoration of circulation results in oxidative damage from the oxygen rather than restoration of normal function. As defined by the present specification in paragraph [0027], atherosclerosis includes arteriosclerosis characterized by a combination of changes in the intima of arteries, such as accumulation of lipids, complex carbohydrates, blood and blood products, fibrous tissue and calcium deposits. Vascular inflammation is defined in the specification in paragraph [0093] as relating to a number of the underlying processes contributing to atherosclerosis which include endothelial dysfunction, vascular proliferation and matrix alteration. Thus, in view of these definitions, Nuijens et al. does not provide a reasonable expectation of success for treating other cardiovascular diseases, except for reperfusion injury, which is related to oxidative injury, not accumulation of lipids, complex carbohydrates, blood or blood products, fibrous tissue, calcium deposits, endothelial dysfunction, vascular proliferation or matrix alteration. As required by the substantial evidence rule, if the Examiner continues to maintain that Nuijens

et al. suggests that lactoferrin can be used to treat atherosclerosis and vascular inflammation as defined by the present specification, then Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in Nuijens et al. *See, In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Yet further, if the Examiner continues to maintain that it would have been obvious to one of ordinary skill art at the time the invention was made that treating reperfusion injury would relate to treating atherosclerosis and vascular inflammation, then the Examiner is referred to MPEP 2144.03 and *In re Zurko* (258 F.3d 1385, 59 USPQ2d 1697 (Fed. Cir. 2001)), which states that an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. Thus, the Examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. *In re Chevenard*, 139 F.2d 713, 60 USPQ 241 (CCPA 1943). *In re Soli*, 317 F. 2d 941, 945-946, 137 USPQ 797, 800 (CCPA 1963). Moreover, if the Applicants adequately traverse the Examiner's assertion of official notice, the Examiner must provide documentary evidence in the next Office Action if the rejection is to be maintained. See 37 CFR §1.104 (c)(2) and *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697. If the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR §1.104(d)(2).

In conclusion, the cited reference does not suggest all the claim limitations of independent claim 1, and thus a *prima facia* case of obviousness has not been established. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Further, all the dependent claims are also non-obvious since all the limitations of the independent claim are not suggested by the above references. Thus, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02726US2 from which the undersigned is authorized to draw.

Dated: June 21, 2005

Respectfully submitted,

By _____

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